New Inventions

The Surgical Isolator

J. McLAUCHLAN, M. F. PILCHER, P. C. TREXLER, R. C. WHALLEY

British Medical Journal, 1974, 1, 322-324

Summary

A plastic film isolator has been developed which is intermediate between a half-suit and an arm isolator. Used for orthopaedic surgery in an aseptic environment few operating difficulties have been found, and an extended trial of its use should be carried out to assess its effect on the incidence of postoperative wound infection.

Introduction

The disastrous results of postoperative wound infection after surgery for total hip replacement have stimulated orthopaedic surgeons to re-examine conventional operating theatre techniques.

In an exhaust-ventilated theatre the air contains as many as 750 to 1,500 particles/m³ which may result in several hundred organisms entering the surgical wound every hour.¹ Positive-pressure ventilation will reduce this figure to 200 to 350 particles/m³, and a further reduction can be obtained by simply reducing unnecessary movement in the theatre. The Charnley-Howarth enclosure with 300 air changes per hour can apparently reduce the number of particles in the air to one or less/m³.²

The air in the operating theatre, though an important source of infection, is not the only means of wound contamination. Potentially infected particles falling from the hair, and the passage of organisms through damp gowns and masks and through punctured gloves, are also hazards—particularly if the surgeon or a member of his team is a carrier of staphylococci.³ In the Charnley-Howarth system the surgical team wear impervious gowns which cover the head and body, and have an air exhaust system and a Perspex window instead of a conventional mask. The extension of the body exhaust system to accommodate the patient⁴ has eliminated airborne organisms in the region of the wound, and completes the impervious system used to protect the operating field, virtually forming an isolator.

A simple surgical isolator has been designed to eliminate so far as possible all known routes of wound contamination,

by isolating the surgical wound and the instruments within an envelope of plastic film inflated with sterile filtered air. It has been developed from techniques used to rear germ-free laboratory animals.⁵ The principle has been applied to surgery before,⁶ but has not been widely accepted because of the complexity and expense involved.

In Levenson's isolator each member of the surgical team is enclosed in a plastic half-suit. One of the first models we used was a small, simple bag into which only the forearms and hands of the surgeon and of his assistants were inserted. The present isolator is a compromise between these two extremes. We have used it mainly for total hip replacement, but there is no reason why the system should not be used in other high risk situations.

Present Appliance

The basic unit is a presterilized disposable plastic film envelope 240 cm in length and 90 cm in diameter with a surgical drape forming a panel in the floor and clear plastic forming the roof (fig. 1). The envelope is inflated with sterile filtered air which escapes through a flutter valve in the roof of the isolator to maintain a continuous circulation of air. A series of sleeves are let into the sides of the envelope to provide access for the surgical team.

A special table for instruments is placed at the foot of the operating table on which the supply end of the isolator is mounted, and beneath this table are housed the pump and filter. The blower, which is driven by a $\frac{1}{2}$ h.p. electric motor, supplies air at 3.24 m³/min at a pressure of 12.5 cm water. The filter is an ultra-high-efficiency type 30 cm by 30 cm by 15 cm. The air changes in the envelope of the isolator are about 60 per hour, so that drying of the wound is not a problem.

At the supply end of the isolator is the air-supported entry port, through which sterile instruments and supplies are introduced. Next to it is a pair of sleeves fitted with heavy-duty rubber gloves.

Methods

To prepare the theatre the instrument table is placed in position, and the prepacked, gamma-irradiated isolator is removed from its outer wraps, unfolded, connected to the air supply aseptically, and slowly inflated. The scrub-nurse enters the sleeves which are fitted with gloves. The flutter valve and the entry port are opened and the nurse receives the instruments and other supplies through the port. The outer wraps are removed by an assistant in the stream of sterile air issuing from the entry port and the packs are taken by the scrub-nurse.

The sleeves along each side of the isolator end blindly at the cuff. Gloves of the appropriate size are now fitted to the

Aberdeen Royal Infirmary, Aberdeen AB9 2ZB

J. McLAUCHLAN, F.R.C.S., Senior Orthopaedic Registrar

Hackney and East London Hospital Groups

M. F. PILCHER, F.R.C.S., Consultant Orthopaedic Surgeon

Royal Veterinary College, London NW1 0TU

P. C. TREXLER, M.S., Reader in Gnotobiotics

Redhill and Crawley Hospital Groups

R. C. WHALLEY, F.R.C.S., Consultant Orthopaedic Surgeon

FIG. 1—Diagrammatic representation of isolator.

sleeves by the scrub-nurse. Four-inch metal rings are slipped into the cuffs of the gloves which are then placed against the blind ends of the sleeves. The sleeve is evaginated carrying glove and ring with it, and the two are held together and sealed with tape applied from the outside by an assistant. When the surgeon is ready the end of the sleeve which forms a diaphragm across the cuff of the glove is torn away and the surgeon puts on the glove. A second pair of gloves may be used if desired.

Electric leads and a hose for suction or for compressed air are easily passed from the inside of the envelope through a cone in the plastic wall, to which they are securely taped by an assistant nurse. Several bags are sealed into the isolator wall to receive waste materials and sponges, which are removed from the lower ends of the bags without danger of contamination to the isolator.

The patient is anaesthetized, prepared, and draped in the usual way. The isolator is inflated and the skin of the operation site is sprayed with adhesive. The surgical drape in the floor of the isolator is uncovered and stuck to the operation site and secured with tapes around the waist and leg of the patient. The drape may be further secured by skin-towels after the skin incision has been made. The surgeon and his assistants enter the appropriate sleeves, and the operation can begin (fig. 2). Alternatively, they may take up their positions earlier and direct the application of the drape to the skin from within the isolator.

The whole operation is carried out with the surgical team separated from the operation site by a continuous layer of plastic film and surgical glove. At the end of the procedure a wound isolator can be applied as a surgical dressing to prevent wound contamination after the patient returns to the ward.

The air in the isolator is at present being sampled with a Hawksley-Gelman air sampler, and two settle plates are placed inside the envelope. In 30 consecutive cases these samples were all sterile. Swabbing of the wound at all stages of the operation with throat swabs or bandage agar plates have shown no evidence of contamination in the depths of the wound, but organisms such as *Staphylococcus albus* have been picked up from the skin edges.

Gloves are tested for punctures at the end of the operation and finger smears are taken from the surgical team. Though pathogenic organisms such as *Staph. aureus* may be found on the hands no evidence of their escape into the isolator has been found, and since it has been routine practice to wear two pairs of gloves no case of puncture of both gloves has been found.

Conclusions

This simple device has been used for nearly 100 total hip replacements as well as for several other procedures, such as meniscectomy, hip pinning, and total knee replacement. The

FIG. 2—Isolator in use.

operation is not made particularly difficult, though the overall operating time is probably increased, and vision through the clear plastic is excellent. The main difficulty is that manipulations of the leg are sometimes hampered by the plastic.

The principle of the isolator has been amply proved in veterinary practice. What is now required is an extended trial of the human surgical isolator to assess the long-term effect on the incidence of postoperative wound infection.

The apparatus and isolators are made by the medical engineering division of Vickers Ltd., and are available to surgeons interested in taking part in such a trial. The capital outlay is a fraction of that for other clean air systems and the cost of the disposable isolator should compare favourably with that of a hip prosthesis.

We wish to pay tribute to the invaluable help given by our nursing staff, particularly Mrs. J. M. Hodgson, Miss C. Hannon, Miss M. Begg, and Mrs. K. C. Grills. Without their co-

operation and enthusiasm the surgical isolator could never have been developed. We also thank our laboratory staffs for the bacteriological investigations.

This work has been financially supported by the National Research Development Corporation.

References

- 1 Blowers, R., *Infection in Hospitals, Epidemiology and Control*, ed. R. E. O. Williams, and R. A. Shooter, p. 199. Oxford, Blackwell Scientific, 1963.
- 2 Charnley, J., and Eftekhari, N., *British Journal of Surgery*, 1969, 56, 641.
- 3 Devenish, E. A., and Miles, A. A., *Lancet*, 1939, 1, 1088.
- 4 Howorth, H., *Reinraumtechnik I*, p. 24. Baden, Schweizerische Gesellschaft für Reinraumtechnik, 1973.
- 5 Trexler, P. C., and Reynolds, L. I., *Applied Microbiology*, 1957, 5, 406.
- 6 Levenson, S. M., et al., *American Journal of Surgery*, 1962, 104, 891.
- 7 Charnley, J., *Journal of Clinical Orthopaedics and Allied Research*, 1972, 87, 167.
- 8 Levenson, S. M., Trexler, P. C., Laconte, M. L., and Pulaski, E. N., *American Journal of Surgery*, 1964, 107, 710.
- 9 Trexler, P. C., *Lancet*, 1973, 1, 91.

Any Questions?

We publish below a selection of questions and answers of general interest

Complications of Anticholesterol Treatment

A patient on a low cholesterol diet for three years and clofibrate for two years has developed both biliary and renal calculi. Is any connexion known between this treatment and the formation of stones?

There is no known connexion between a low cholesterol diet or clofibrate with the formation of renal calculi. There have been reports of an increased incidence of gall stones in patients receiving a polyunsaturated fat diet.¹ There is evidence also that both a polyunsaturated fat diet and clofibrate decrease the solubility of Cholesterol in bile. Clofibrate increases the excretion of cholesterol through the biliary tract whereas bile acid excretion via the faeces is reduced.² There is, however, no firm clinical evidence of an association between this drug and gall stones. One difficulty in determining whether a dietary or drug regimen increases the incidence of gall stones is that they are asymptotically present in many apparently healthy middle-aged adults though exactly how many has not been established.³ Formal studies to determine whether a low cholesterol diet, a polyunsaturated fat diet, or clofibrate increase the incidence of gall stones have not been made.

¹ Dayton, S., Pearce, M. L., Hashimoto, S., Dixon, W. J., and Tomiyasu, U., *American Heart Association Monograph No. 25*, 1969.

² Grundy, S. M., Ahrens, E. H., Salen, G., Schneibman, P. H., and Nestel, P. J., *Journal of Lipid Research*, 1972, 13, 531.

³ Heaton, K. W., *Clinics in Gastroenterology*, 1973, 2, 67.

Effectiveness of Chemical Closets

How effective are the chemicals used for chemical closets? Are they in any way harmful when spread on the soil?

The chemicals used in chemical closets are usually based on formaldehyde, either as solutions in strengths up to 40% w/v, or in powder form. Phenolic coal-tar preparations are also used, and at least one popular preparation is based on caustic soda. A British Standard¹ covers certain properties of these chemicals. Recent work suggests that formaldehyde-based

agents can control bacterial multiplication under closet conditions for a few days but are not so effective as phenolic agents in killing typical faecal bacteria rapidly.

At a large mental hospital in South Wales, "Destrol" chemical closets, using a chemical based on chlorxylenol, were installed in 1963 for the exclusive use of known typhoid excretors.² The contents were added to the remaining sewage of the hospital, and after passing through the hospital sewage treatment plant were discharged to a small stream.³ Samples collected from the stream below the point of discharge were positive for *Salmonella typhi* on about 10% of occasions during five years, though for 24 months from March 1969 no *S. typhi* were found in 63 consecutive samples. When operation of the closet agitators was left for a period to the patients the positive samples rose to 41% but when the staff were made responsible for operating the agitators the figure fell to about 10%. Unfortunately, chemical closets installed in caravans are not usually fitted with agitators. Thus unnecessary risks should not be taken in the disposal of chemical closet contents.

If the contents are spread on the soil, both the chemical and the excreta will be broken down by soil bacteria in the course of some weeks, provided the soil is not overloaded.⁴ The soil will be toxic to plants for about two to six weeks, depending on temperature and rainfall, but will recover, and in the long run will cause benefit by killing soil pests and plant pathogens, and by the manurial value of the excreta. However, pathogenic bacteria have been shown to survive for many weeks in faeces in contact with soil, though they will die progressively. There is also a possibility of pathogenic ova—for example, hookworm or ascaris—being present in faeces. If full benefit is to be obtained from chemical closets, they must be properly used, and the contents should be buried in the ground rather than spread on the surface. Better still, they should be removed by the local authority for treatment, and caravan centres should be prepared to pay for this service.

¹ British Standards Institution, *Chemical Preparations for Chemical Closets (Portable Type) Excluding those for use in Aircraft*, B.S. 2893. London, British Standards Institution, 1957.

² Harvey, R. W. S., and Price, T. H., *Journal of Hygiene*, 1972, 70, 439.

³ Gell, P. G. H., Hobbs, B. C., and Allison, V. D., *Journal of Hygiene*, 1945, 44, 120.

⁴ Hall, N. M., and Clegg, L. F. L., *Proceedings of the Society for Applied Bacteriology*, 1949, 12 (2), 105.